

REMARKS

Claims 2-9 are pending in this application. Claim 9, which is directed to an alternative method for using a single oligonucleotide in an automated assay, has been added to the application. No new matter has been added to the application by this claim amendment.

I. NO NEW MATTER HAS BEEN ADDED TO THE APPLICATION

The examiner objected to the specification for including new matter. Specifically, the examiner's position is that the preliminary amendment filed on June 23, 2003 introduces new matter into the disclosure in the form of the annealing of at least one primer.

New matter has not been added to the specification by way of the June 23, 2003 preliminary amendment. Claims 2-8 find support in at least Application Example III. The PCR procedure described in Example III uses two primers. One oligonucleotide primer is used to determine the beginning of the region to be amplified and the second oligonucleotide primer determines the end of the regions to be amplified. By default, therefore, Example III discloses "annealing at least one primer" because primers are annealed independently of one another in a PCR procedure. In addition, as discussed below, one of ordinary skill in the art would understand that it is unnecessary to use two oligonucleotide primers in order to perform polymerase – mediated extension on the annealed oligonucleotide primer target.

One skilled in the art at the time of the invention would understand that are a myriad of PCR procedures are available to scientists and that two primers are not always necessary in PCR amplification/detection procedures. U.S. Patent No. 5,599,674, for example, discloses low stringency PCR techniques that use a single oligonucleotide primer. (See Appendix A). Asymmetric PCR is another PCR procedure that may be performed with a single oligonucleotide primer. A copy of the Wikipedia description of PCR attached at Appendix B includes a description of Asymmetric PCR. The description indicates that in Asymmetric PCR amplification is carried out with a great excess of a primer chosen for the desired strand. (See page 7 of Appendix B). One of ordinary skill in the art would understand that asymmetric PCR is useful using only a single oligonucleotide primer.

The specification description of PCR techniques is sufficient to apprise one of skill in the art at the time of the invention that the claimed invention is useful with all known PCR

techniques at the time of the invention including Asymmetric PCR techniques. For at least this reason, the claim amendments of June 23, 2003 do not add new matter to the application.

II. TRAVERSE OF THE 112, 1st PARAGRAPH REJECTION

The examiner rejected claims 2-8 under 35 USC 112, first paragraph for failure to comply with a written description requirement. In particular, the examiner takes the position that the specification does not describe how only one oligonucleotide primer is annealed or that the processing of doing such would yield any productive result. Moreover, the examiner has rejected claims 2-8 under 35 USC 112, first paragraph for failing to enable the claimed invention. Namely, the examiner is of the position that there is no indication in the specification that annealing only one primer to the target molecule is sufficient or even possible to perform or achieve the desired results as disclosed.

As discussed in Section I above, there are PCR techniques known to those skilled in the art that are performed with a single primer. Moreover, the single primer procedures, such as Asymmetric PCR and the method disclosed in the attached '674 patent are performed generally in accordance with the procedures set forth in Example III except that a second oligonucleotide primer is not be used. For this reason, the general description of PCR techniques in the specification and in Example III are sufficient to describe and enable one of skill in the art to practice the invention with PCR techniques that use only a single oligonucleotide primer.

III. THE DOUBLE PATENTING REJECTION

The examiner rejected claims 2-8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,582,962. This rejection is overcome by filing Terminal Disclaimer with respect to U.S. Patent No. 6,582,962 on the same date as the filing of this Reply. A copy of the Terminal Disclaimer is attached hereto at Appendix C.

IV. NEW CLAIM 9

New claim 9 has been added to the application in this Reply. New claim 9 identifies an additional process that uses a single oligonucleotide primer. That procedure is disclosed in the specification and specifically in application Example II.

CONCLUSION

For the reasons indicated above, claims 2-9 are believed to be patentable. Favorable reconsideration and allowance of all pending application claims is, therefore, courteously solicited.

Respectfully submitted,

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